

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Maryann T. Puglielli on February 18 and 24, 2009.

The application has been amended as follows:

In the specification, page 1, before line 1, insert ---This application claims priority from provisional application 60113536 filed 12/22/1998 and claims foreign priority to PA199801709 filed 12/22/1998.---

In the IDS filed on March 21, 2000, insert ---,26/03/1996-- at the end of NPL reference beginning with "Derwent".

Claim 15, last paragraph at step (e), line 2, "(a), (b), or (c)" is replaced with --(b), (c) or (d)--.

Claim 21, step (e), last line, insert – to obtain a measurement of the carrier-bound IgE-containing complexes-- after "complexes".

Claim 21, last line, insert --, and wherein the measurement is used as a basis for monitoring and evaluating the immunological status of the subject-- .

Claim 22, step (e), last line, insert – to obtain a measurement of the carrier-bound IgE-containing complexes-- after "complexes".

Claim 22, last line, insert --, and wherein the measurement is used as a basis for monitoring and evaluating the immunological status of the subject-- .

Claim 23, last line, "IgE" is replaced with --the IgE antibody--.

The following is an examiner's statement of reasons for allowance:

the prior arts fail to teach:

A method of detecting and/or quantifying an IgE antibody specific to a ligand in the form of an antigen, an antibody, or a hapten in a liquid sample suspected to contain the IgE antibody comprising the steps of:

- (a) contacting (i) the sample with (ii) a free dissolved ligand in the form of an antigen, an antibody, or a hapten to form a mixture I comprising complexes that comprise the IgE antibody and the ligand (IgE-containing complexes),
- (b) mixing the mixture I with a carrier to which is bound (iii) an IgE receptor, wherein said IgE receptor is CD23 (FcERII), to form a mixture II comprising carrier-bound IgE-containing complexes,
- (c) separating the carrier-bound IgE-containing complexes from the mixture II, and
- (d) determining the amount of the carrier-bound IgE-containing complexes formed by detecting a label present in the carrier-bound IgE-containing

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complexes, wherein the label to be detected is associated with the ligand or the IgE antibody and wherein the label to be detected is added to the complexes present in steps (a), (b), or (c) and does not form part of the carrier.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Pensee T. Do/  
Examiner, Art Unit 1641

/Jacob Cheu/  
Primary Examiner, Art Unit 1641